REMARKS

Claims 2 to 7; 21; 23; 31; and 38 have been amended. Claims 1; 8 to 20; 22; 24 to 30; 32 to 37; and 39 have been canceled. New claims 40 to 48 have been added.

Claims 2 to 7; 21; 23; 31; 38; and 40 to 48 (a total of 19 claims) remain for examination. The sole independent system claim is claim 2. Claim 38 is a method claim that is dependent upon claim 2.

The Examiner's time and attention during a personal interview conducted April 26, 2006 is acknowledged and appreciated. During the interview, Lee Bolduc, one of the named inventors, discussed the challenges of placing a prosthesis within an endovascular region or hollow body organ, e.g., within an aorta to treat an abdominal aortic aneurism (AAA).

One prior art problem that Mr. Bolduc discussed was the slippage of the prosthesis within the endovascular region after implantation and/or leakage of blood from an end of the prosthesis into the aneurism. Prior art solutions include the use of stents with tissue piercing barbs (see, e.g., Revelas US 5,968,053, listed on the attached Supplemented Information Disclosure Statement); staples or "rivets" (see, e.g., Dereume et al. US 5,639,278 – col. 7/7 to 14, listed on the attached Supplemented Information Disclosure Statement, or Taheri US 5,042,707, of record); fasteners that do not pierce and penetrate tissue but are instead inserted through holes preformed in the vessel wall (see, e.g., Tanner et al US 5,944,750, or record); and tissue piercing helical fasteners (see, e.g., Parodi US 6,336,933, listed on the attached Supplemented Information Disclosure Statement).

As explained by Mr. Bolduc, the endovascular delivery and implantation of tissue piercing fasteners posed their own technical problems.

Mr. Bolduc described one of the technical problems, which concerns orienting the tissue piercing fastener for implantation with respect to a vessel wall. As explained by Mr. Bolduc, a fastener is desirably oriented for implantation at an angle with respect to the axis of the endovascular region itself. Prior art has addressed with this problem by bending or deflecting the fastener applier itself. See, e.g., Taheri '707, which steers the end of the fastener applier, or Parodi '933, which pre-bends the end of the fastener applier. As explained by Mr. Bolduc, deflecting the fastener applier adds complexity to the overall assembly. One look at the articulated "stove pipe" assembly of Taheri '707 bears this out.

In this context, Mr. Bolduc described one aspect of the invention defined in amended claim 2, which is directed to orienting the tissue piercing fastener with respect to a vessel wall without directly deflecting the fastener applier itself, but rather by providing a directing device having a deflectable distal end along which the fastener applier is introduced.

Mr. Bolduc described another one of the technical problems in terms of concept Mr. Bolduc called "force resolution." Penetration and implantation of a tissue piercing fastener into tissue requires the fastener applier to exert an implantation force at or near the prosthesis and vessel wall. Mr. Bolduc described his recognition – not contemplated by the prior art -- that the implantation force of the fastener applier needs to be resolved in some manner within the vessel or hollow body organ, to provide positional stability and resist unintended movement of the fastener applier relative to the implantation site. As explained by Mr. Bolduc, a resolution force needs to be applied to counteract and/or oppose the implantation force of the fastener applier. These matters are also described in the Specification, pages 23 to 26.

In this context, Mr. Bolduc described another aspect of the invention defined in amended claim 2, which is directed to resolving at least a portion of the implantation force within the vessel lumen (or other hollow body organ) itself by applying a resolving force in a direction different than the implantation force.

These aspects of the invention, defined in amended claim 2, solved the technical problems of orientation and force resolution. Sample components of a system as defined by amended claim 2 were shown to the Examiner, and their successfully use in implanting a prosthesis in humans for the treatment of AAA was explained.

Amended claim 2 defines a system comprising a fastener attachment assembly for a tissue-piercing fastener having a sharpened distal tip for piercing and penetrating tissue. As defined in amended claim 2, the fastener assembly comprises two components – an intraluminal directing device and an intraluminal fastener applier separate from the directing device The directing device defines an access path along which the fastener applier is introduced. The directing device has a deflectable distal region. The fastener applier includes an actuated member that is selectively operable to generate an implantation force in an implantation force direction to implant the tissue-piercing fastener. As defined in amended claim 2, the tissue-piercing fastener is implanted by causing the sharpened distal tip to pierce and penetrate tissue. As further defined in amended claim

2, the system includes means associated with the fastener attachment assembly for applying a resolving force in a direction different than the implantation force direction within the targeted endovascular region to resolve at least a portion of the implantation force.

Disclosure of the means plus function element is found in Specification page 23, line 32 to page 26, line 32.

The prior art, most particularly Taheri '707 and Tanner '750, were discussed with the Examiner during the interview.

As before stated, Taheri '707 does not teach or suggest a two component system, as defined in amended claim 2, comprising an intraluminal directing device having a deflectable distal region and an intraluminal fastener applier separate from the directing device along which the fastener applier is introduced. Teheri directly deflects the fastener applier itself. Taheri also does not teach or suggest or comprehend the concept of force resolution. A look at Fig. 12 of Taheri bears this out – Taheri is oblivious to the fact that the implantation force of the fastener applier needs to be resolved in some manner within the vessel or hollow body organ to provide positional stability and resist unintended movement of the fastener applier relative to the implantation site.

Tanner '750 is critical of Taheri '707 in several respects (see col. 2, lines 45 to 67), but does not perceive one of the weakness being a lack of force resolution. In fact, Tanner '750, like Taheri '707 is oblivious to the need to resolve the force of implantation of a tissue-piercing fastener within a vessel. In the case of Tanner '750, this shortcoming is understandable, because Tanner '750 does not fairly teach or suggest, as defined in amended claim 2, a tissue-piercing fastener having a sharpened distal tip for piercing and penetrating tissue, which is implanted by an actuated member by causing the sharpened distal tip to pierce and penetrate tissue. Tanner '750 teaches away from the use of a tissue-piercing fastener, as defined in amended claim 2, and instead teaches the creation of a plurality of treatment specific holes in the vessel wall, using e.g., a laser, through which a fastener is inserted without itself piercing and penetrating the tissue (see, e.g., col. 5, lines 49 to 62; col. 17, lines 36 to 42; col. 18, lines22 to 26; col. 18, lines 44 to 52; col. 19, lines 24 to 33; col. 21, line 34 to col. 23, line 19).

During the interview, the paragraph found in Tanner '750 col. 23, lines 20 to 31 was discussed. In this paragraph, Tanner alludes to different types of fasteners, which include "screw-type fasteners." This bare reference of a "screw-type fastener" does not, in the overall context of

Tanner '750 as a whole, fairly teach or suggest implantation of a fastener by causing a sharpened distal tip of a tissue-piercing fastener to pierce and penetrate tissue. (as defined in amended claim 2). What Tanner '750 teaches is the pre-formation of holes within a vessel wall and the insertion fasteners through these holes, not implantation by applying an implantation force that causes a sharpened distal tip of a fastener to itself pierce and penetrate tissue. In this respect, the central theme of Tanner '750 actually teaches away from the invention defined in amended claim 2.

Likewise, Revelas '053 and Dereume '278 and Parodi '933 do not teach or suggest a two component system, as defined in amended claim 2, comprising an intraluminal directing device having a deflectable distal region and an intraluminal fastener applier separate from the directing device along which the fastener applier is introduced, which two component system further provides a means for resolving an implantation force, as further defined in amended claim 2..

At the conclusion of the interview, the applicant agreed to amend the draft amendment to claim 2 (submitted prior to the interview) by adding in line 3, after fastener "having a sharpened distal tip for piercing and penetrating tissue" and in line 12 replacing "into tissue" with "by causing the sharpened tip to pierce and penetrate this tissue." Claim 2, as amended, includes these features.

For these reasons, applicant believes that Claims 2 to 7; 21; 23; 31; 38; and 40 to 48 are in condition for allowance. As expressed during the interview, if the Examiner believes that questions or matters of clarification remain, applicant believes that such matters can be handled expeditiously by an interview by telephone to advance prosecution of this case, and the applicant remains committed to proceed on that basis.

Respectfully Submitted,

By_____
Daniel D. Ryan
Registration No. 29,243

RYAN KROMHOLZ & MANION, S.C.
Post Office Box 26618
Milwaukee, Wisconsin 53226
(262) 783 - 1300
Customer No.: 26308